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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,542	12/11/2003	Stephen C. Wardlaw	5169-0011-1-1	7739

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EXAMINER	
BHAT, ADITYA S	
ART UNIT	**PAPER NUMBER**
2863	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,542	WARDLAW ET AL.	
	Examiner	Art Unit	
	Aditya S. Bhat	2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8-10,14 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8-10,14 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 8-10, 14 and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Westgard et al. (USPN 5,937,364)

With regards to claim 1, Westgard et al. (USPN 5,937,364) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument; The Westgard reference does not explicitly disclose this sending quality control specimens to the operator but the reference does teach using control samples to evaluate a analytical instrument. It would be inherent to send the quality control specimen to the operator of the analytical instrument in order to evaluate the instrument.

communicating control data to the analytical instrument,(Col. 2, lines 52-59) wherein the control data includes characteristic values for the specimens, (col. 2, lines 43-47) and wherein the control data is created independently of the analytical instrument; (Col. 2, lines 43-59)

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; (Col. 2 lines 57-61),

performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine functional status of the analytical instrument; (col. 2, liens 52-55) and

providing notice to an operator regarding the functional status of the analytical instrument. (Col. 2, lines 33-35).

With regards to claim 19, Westgard et al. (USPN 5,937,364) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument (see above)

communicating control data to the analytical instrument, (Col. 2, lines 52-59) wherein the control data includes acceptable operating standards, (col. 3, lines 19-21) and wherein the control data is created independently of the analytical instrument; (Col. 2, lines 43-59)

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data (Col. 2 lines 57-61),

performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine functional status of the analytical instrument; (col. 2, liens 52-55) and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 2, lines 33-35).

With regards to claim 20, Westgard et al. (USPN 5,937,364) teaches a quality control system for analytical instruments, said system comprising:

one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen and the one or more characteristic values (Col.3 lines 43-54);

an analytical instrument, (Col. 2, lines 54-55) having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values (Col. 2 lines 57-62) and

means for notifying an operator regarding the functional status of the analytical instrument (Col. 2, lines 33-35).

With regards to claim 24, Westward et al. (USPN 5,937,364) teaches method for providing quality control in an analytical instrument, said method comprising the steps of:

providing one or more quality control specimens and control data that includes characteristic values for the one or more quality control specimens, to an operator of the analytical instrument, wherein the control data is created independently of the analytical instrument; (col. 2, lines 43-62)

analyzing at least one of the one or more quality control specimens and thereby creating instrument analysis data (col. 2, lines 52-55) and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 2, lines 33-35).

With regards to claim 2, Westgard et al. (USPN 5,937,364) teaches the evaluation being performed without operator input (Col. 1, lines 56-59).

With regards to claim 3, Westgard et al. (USPN 5,937,364) teaches the evaluation is performed using routines preprogrammed within the analytical instrument (Col. 1, lines 56-59).

With regards to claim 5, Westgard et al. (USPN 5,937,364) teaches the step of performing an evaluation within the analytical instrument of includes a comparison of the characteristic values for the one or more quality control specimens and one or more characteristic values created within the instrument analysis data (Col. 2, lines 43-47).

With regards to claim 8 Westgard et al. (USPN 5,937,364) teaches the control data is communicated to the analytical instrument from a remote source via an electronic communications connection (Col. 1, lines 45-61).

With regards to claim 9, Westgard et al. (USPN 5,937,364) teaches the analytical instrument that the quality control specimen is for quality control purposes (Col. 2, lines 43-47).

With regards to claim 10, Westgard et al. (USPN 5,937,364) teaches the analytical instrument that the quality control specimen is for quality control purposes is performed without operator input (Col. 1, lines 56-59).

With regards to claim 14, Westgard et al. (USPN 5,937,364) teaches the step of providing a preprogrammed schedule for quality control procedures to analytical instrument (Col. 1, lines 56-59).

With regards to claim 21, Westgard et al. (USPN 5,937,364) teaches the means for performing an evaluation of the analytical instrument within the analytical instrument does not require input from an operator (Col. 1, lines 56-59).

With regards to claim 22, Westgard et al. (USPN 5,937,364) teaches evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator (Col.1, lines 56-59).

With regards to claim 23 Westgard et al. (USPN 5,937,364) teaches selectively preventing the reporting of test results in the event the functional status of the analytical instrument is determined to be unacceptable (Col. 2, lines 36-38).

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5, 8-10, 14 and 19-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yundt-Pacheco (USPN 6,549,876) teaches a method of evaluating performance of a hematology analyzer, Aryev et al. (USPN 6,581,012) teaches a automated laboratory software architecture, Okuno et al. (USPN 6,629,060) teaches support method, quality control method and device thereof, Robbins (USPN 6,922,646) teaches a method and system for random sampling and Yundt-Pacheco et

al. (USPN 7,010,448) teaches method and structure for mitigating instrumentation differences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditya S. Bhat whose telephone number is 571-272-2270. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aditya Bhat
January 29, 2007

John Barlow
Supervisory Patent Examiner
Technology Center 2800